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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,000	10/06/2003	Daniel Acschlimann	S/267 DIV	4529

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/680,000	AESCHLIMANN ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-17 and 19-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-17 and 19-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 14, 15 and 19-27 have been amended. Claim 18 is canceled. Claims 14-17 and 19-27 are pending. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 – 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17 and 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

Claim 14 has been amended to recite the limitation "such that the degree of substitution is more than 5%" and cites passages in the specification discussing ranges of 10-25% and ~20-25% modification as support for this limitation. The limitation recites a range of >5 to 100% modification. The examiner does not agree that the cited ranges provide adequate written description for this newly submitted range and deems this new limitation to be new matter.

Claim Rejections - 35 USC § 112 – 2nd paragraph

Claims 14-17 and 19-27 are rejected again under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims were amended in response to the rejection set forth in the previous Office action, but the amendment does not really address the issue. As noted previously, claim 14 reads such that the product has a side chain attached to the carbonyl carbon which, after the reaction comprises both a nucleophilic groups and some other functional group. However, it is not clear how (as required by claim 15) ammonia—an independent molecule with a trivalent nitrogen—is meant to be bonded to the side chain. This uncertainty calls into question just what is required and what is excluded from the side chain.

Claim Rejections - 35 USC § 102

Claims 14-17 and 19 are again rejected under 35 U.S.C. 102(b) as being anticipated by GUIRE et al (US 5,512,329).

GUIRE teaches the preparation of ANP-EAC-HA by treating HA with EDC and sulfo-NHS to form an activated ester followed by the addition of ANP-EAC-jeffamine. The reaction introduces an arylazide functional group into the HA. See col 10, lines 26-40. This product is crosslinked to form a hydrogel. See example VIII.

Applicant's arguments filed December 1, 2005 have been fully considered but they are not persuasive. Applicant contends that the reference "concern[s] 'substrate surface preparation,'

[and] does not disclose a degree of substitution of its molecules of more than 5%, nor the required crosslinking."

The examiner respectfully disagrees. In example VIII, the reference exemplifies the preparation of HA derivatized with ANP-EAC-PEG-jeffamine, as per the process of Example I, as described above. This results in a substitution level of one photo-group per 5 carboxyl groups, or 20%. This derivative then undergoes photo-crosslinking. This appears to meet the limitations of the claims.

Claim Rejections - 35 USC § 103

Claims 14-16, 19, 21-23 and 27 are again rejected under 35 U.S.C. 103(a) as being unpatentable over RHEE et al (US 5,510,418) and RIGHETTO et al (US 5,856,299).

Applicant's arguments filed December 1, 2005 have been fully considered but they are not persuasive.

Applicant argues that the crosslinking method of Rhee, which relies on the use of hydroxyl groups instead of carboxyl groups, is different from those in the instant invention. Although Applicant may intend to crosslink exclusively via carboxyl derivatization, the claims do not require that the moiety attached to the carboxyl group be involved in the crosslinking or that step c) occur *after* steps a) and b). For example, Rhee teaches the preparation of a HA derivative "GAG-PLYM-NH_2." See Formulas 1-7 and reaction scheme 1. This derivative is then crosslinked. As discussed previously, the reference further suggests covalent attachment of biologically active substances, such as peptides and growth factors. One of ordinary skill would be motivated to prepare such conjugates by the method of Righetto, also discussed previously.

Alternatively, the artisan could prepare the conjugate, as per Righetto and then effect crosslinking *in situ*, as suggested by Rhee. Either of these methods would have been obvious over the combination of Rhee in view of Righetto, as completely in accordance with the instant claims. Righetto teaches up to 100% carboxyl derivatization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the amount of bioactive material incorporated through routine optimization.

Applicant further argues that Righetto teaches away from crosslinking. However, this does not appear to be particularly relevant because this reference is used to teach a method of incorporating a bioactive agent into a product that is either already crosslinked, or to be crosslinked specifically by another method.

Finally, Applicant argues that in the compositions prepared by this method, "derivatized carboxyl groups are crosslinked to form predictable and stable products without affecting the structure or length of the polysaccharide chains." However, the examiner finds no particular limitation regarding structure and chain length.

The examiner notes an "asterisked" footnote at page 11 of Applicant's response regarding a declaration that was submitted in the parent case supporting certain assertions. However, there is no asterisk in the text indicating to what this refers in the present response, nor is the declaration (or an explanation of specifically how it addresses the rejections of record) present with the remarks submitted December 1, 2005. The declaration was available for review in the parent case, but it appears to be limited to addressing structural features of the products and not particularly to the instant method. Furthermore, the scope of the products required by the claims

of the parent is not commensurate with the scope of the products that could be prepared by the instant method.

Claims 14-16 and 19-27 are again rejected under 35 U.S.C. 103(a) as being unpatentable over RHEE et al (US 5,510,418) and RIGHETTO et al (US 5,856,299) in view of HUNZIKER et al (US 5,270,300) and HOHENADL et al (JBC, 1995).

Applicant's arguments filed December 1, 2005 have been fully considered but they are not persuasive.

Applicant does not present any additional response not addressed above. The rejection is maintained for reasons of record.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Patent Examiner
February 17, 2006